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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **Benjamin W. Boldt and Dennis Roscetti**

Serial No.: 09/109,119

Filed: 06/30/98

Group Art Unit: 1655

Examiner: **Jeanine Goldberg**

For: **A Process For Detecting A Known Sequence In Genomic DNA**

AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

This Amendment responds to the Office Action dated December 28, 2000. Kindly amend the application as follows:

In the Specification:

On page 17, line 9, Delete the sequence after the word "modified" and substitute "SEQ ID NO:1"

On page 17, line 10, Delete the sequence after the = and substitute "SEQ ID NO:2"

On page 20, line 30, Delete the sequence after the word "modified" and substitute "SEQ ID NO:3"

In the Claims:

Please amend claims 1, and 13 as follows:

1. (Amended) [A process for testing genomic DNA for conditions, whether inherited or not inherited, comprising:
   a. making a solution comprising the genomic DNA;
   b. adding a primer that hybridizes to a targeted section of the genomic DNA wherein a base at or near the primer 3' end may not hybridize to the genomic DNA;
   c. mixing a DNA polymerase into the solution;

(1)

d. amplifying the section of the genomic DNA if the base at or near the primer 3' end hybridizes;
e. capturing amplified polynucleotide strands to a solid support;
f. detecting captured amplified polynucleotide strands; and,
g. determining a condition based on a result selected from the group consisting of detection of amplified polynucleotide strands and non-detection of polynucleotide strands.]

C1 cont.

1. A process for testing genomic DNA for detecting if at least one base is present, whether inherited or not inherited, comprising:
a. making a solution comprising the genomic DNA;
b. adding a primer that hybridizes to a targeted section of the genomic DNA wherein a base at or within 3 bases of the primer 3' end will hybridize and extend along the genomic DNA if the base is present and will not hybridize if the base is not present;
c. mixing a DNA polymerase into the solution;
d. amplifying the targeted section of the genomic DNA if the base at or within 3 bases of the primer 3' end hybridizes;
e. capturing amplified polynucleotide strands to a solid support wherein the solid support contains probes sequenced to hybridize to amplified product having the base but to not hybridize if the base is not present; and,
f. detecting amplified polynucleotide strands if the base is present and non-detection of polynucleotide strands if the base is not present.

13. (Amended) [A process for detecting a mismatch base in a diagnostic section of genomic DNA for conditions, whether inherited or not inherited, comprising:
a. obtaining the genomic DNA;
b. mixing the genomic DNA with a primer that hybridizes to a targeted section of the genomic DNA wherein a base at or near the primer 3' end may not hybridize to the genomic DNA;
c. amplifying the section of the genomic DNA if the base at or near the primer 3' end hybridizes;
d. capturing amplified polynucleotides to a solid support; and
e. determining a condition based on a result selected from the group consisting of detection of amplified polynucleotide strands and non-detection of polynucleotide strands.]

C2

13. A process for detecting a base in a targeted section of genomic DNA, whether inherited or not inherited, comprising:
a. obtaining the genomic DNA;
b. mixing the genomic DNA with a primer that hybridizes to the targeted section of the genomic DNA wherein a base at or within 3 bases of the primer 3' end hybridizes to the genomic DNA if the base is present;

c. amplifying the targeted section of the genomic DNA if the base at or within 3 bases of the primer 3' end hybridizes;

d. capturing amplified polynucleotide strands to a solid support wherein the solid support contains probes sequenced to hybridize to amplified product having the base but to not hybridize if the base is not present; and,

e. detecting amplified polynucleotide strands if the base is present.

REMARKS

Sequence Rules:

A sequence listing has been added to the application which contains no new matter. The paper copy is the same as the computer readable copy on the supplied diskette.

Objection to the Specification under 35 U.S.C. 112:

In the Office Action, on page 3, claims 1-20 have been rejected under §112.

Applicants have amended independent claims 1 and 13 to remove the terminology considered unclear in the Office Action: "near".

Applicants have amended claim 1 of the application to clarify the detection process.

Accordingly, Applicants believe that the §112 rejections are obviated by the amendments.

Rejection of claims 1-20 under 35 U.S.C. 102-103:

Claims 1-20 have been rejected under §102 and §103 as being anticipated by Newton et al., and other prior art.

Applicants have amended independent claims 1 and 13 to state that the detection method contains two selective hybridization steps: the first step is the terminal base match or mismatch which determines if efficient PCR will take place; the second step is hybridization of the amplified product to probes attached to the plate. The probes are sequenced to hybridize if the target base is present and to not hybridize if the base is not present.

None of the prior art presented contain two selective steps to weed out inefficiently amplified product that can disrupt accurate results. Additionally, there is no suggestion to have two selective steps in the prior art.

Applicants believe that the rejection has been obviated. Therefore claims 1 and 13 along with their dependent claims are believed to be allowable.

The Office Action's objections and rejections are believed to be overcome by this Amendment and Response. In view of Applicants' amendment and discussion, it is submitted that the claims 1-20 should be allowable and Applicants respectfully request an early notice to such effect.

Respectfully submitted,

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